

Notice of Allowability

Application No.

09/928,227

Applicant(s)

MAHAN ET AL.

Examiner

Art Unit

Ginny Portner

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/15/05 and 9/6/05 interview.
2. ☒ The allowed claim(s) is/are 1,3,6,9,11,16-18 and 55-58; now claims 1-12.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>herewith</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

1. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on September 6, 2005, Mr. David J. Aston, Registration Number 28,051 requested an extension of time for 1 MONTH(S) and authorized the Director to charge Deposit Account No. 16-1331 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Please cancel claims 24, 28-32 and 47-54.

Please add the following claims:

⁹
~~55~~. (New) A composition comprising a pharmaceutically acceptable excipient together with an attenuated, pathogenic bacteria having reduced bacterial virulence, wherein the bacteria is altered by an agent that prevents the bacteria's *dam* gene expression thereby altering the bacteria's native level of methylation of adenine in a GATC tetranucleotide of the bacteria,

wherein the alteration is selected from the group consisting of: a deletion within a *dam* gene of the bacteria, an insertion within a *dam* gene of the bacteria, and an agent bound to a native *dam* nucleic acid sequence of the bacteria and preventing expression of a *dam* gene, and

the bacteria is selected from the group consisting of: *Bordetella*, *Haemophilus*, *Neisseria*, *Pasteurella*, *Shigella*, *Treponema*, and *Yersinia*.

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¹⁰
~~56.~~ (New): The composition of claim ⁹~~55~~ wherein the alteration is a deletion within a *dam* gene of the bacteria.

¹¹
~~57.~~ (New): The composition of claim ⁹~~55~~ wherein the alteration is an insertion within a *dam* gene of the bacteria.

¹²
~~58.~~ (New): The composition of claim ⁹~~55~~ wherein the alteration is an agent bound to a native *dam* nucleic acid sequence of the bacteria and preventing expression of a *dam* gene.

The following is an examiner's statement of reasons for allowance:

The instantly claimed invention is directed to a method of producing an attenuated *Bordetella*, *Haemophilus*, *Neisseria*, *Pasteurella*, *Shigella*, *Treponema*, and *Yersinia*, wherein the attenuation is accomplished through the introduction of an alteration by an agent that prevents the bacteria's *dam* gene expression thereby altering the bacteria's native level of methylation of adenine in a GATC tetranucleotide of the bacteria, wherein the alteration is selected from the group consisting of: a deletion within a *dam* gene of the bacteria, an insertion within a *dam* gene of the bacteria, and an agent bound to a native *dam* nucleic acid sequence of the bacteria and preventing expression of a *dam* gene.

The prior art of record does not teach, nor reasonably suggest the specific species of attenuated bacteria, wherein the attenuation is accomplished through specific genetic alterations of the adenine methyltransferase gene (*dam* gene) for each bacteria which results in the bacteria's native level of methylation of adenine in the DNA sequence "GATC" being altered. The specific alternation being accomplished through chemical means, deletion of the coding sequence for the adenine methyltransferase protein or by insertion of a sequence within the coding sequence (gene) that disrupts the native level of expression of the adenine methyltransferase protein.

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2. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
September 12, 2005


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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